

**CONFERENCE COMMITTEE REPORT
DIGEST FOR EHB 1382**

Citations Affected: IC 5-10-8-15; IC 12-15-5-9.2; IC 27-8-25; IC 27-13-7-20.2.

Synopsis: Coverage related to clinical trials. Requires coverage for certain services related to cancer clinical trials under a state employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a health maintenance organization contract. **(This conference committee report: (1) makes corrections and technical changes; and (2) defines certain terms.)**

Effective: July 1, 2009.

CONFERENCE COMMITTEE REPORT

MR. SPEAKER:

Your Conference Committee appointed to confer with a like committee from the Senate upon Engrossed Senate Amendments to Engrossed House Bill No. 1382 respectfully reports that said two committees have conferred and agreed as follows to wit:

that the House recede from its dissent from all Senate amendments and that the House now concur in all Senate amendments to the bill and that the bill be further amended as follows:

- 1 Delete everything after the enacting clause and insert the following:
- 2 SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE
- 3 AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
- 4 1, 2009]: **Sec. 15. (a) As used in this section, "care method" means**
- 5 **the use of a particular drug or device in a particular manner.**
- 6 **(b) As used in this section, "clinical trial" means a Phase I, II,**
- 7 **III, or IV research study:**
- 8 **(1) that is conducted:**
- 9 **(A) using a particular care method to prevent, diagnose, or**
- 10 **treat a cancer for which:**
- 11 **(i) there is no clearly superior, noninvestigational**
- 12 **alternative care method; and**
- 13 **(ii) available clinical or preclinical data provides a**
- 14 **reasonable basis from which to believe that the care**
- 15 **method used in the research study is at least as effective**
- 16 **as any noninvestigational alternative care method;**
- 17 **(B) in a facility where personnel providing the care method**
- 18 **to be followed in the research study have:**
- 19 **(i) received training in providing the care method;**
- 20 **(ii) expertise in providing the type of care required for**
- 21 **the research study; and**
- 22 **(iii) experience providing the type of care required for**

- 1 the research study to a sufficient volume of patients to
 2 maintain expertise; and
 3 (C) to scientifically determine the best care method to
 4 prevent, diagnose, or treat the cancer; and
 5 (2) that is approved or funded by one (1) of the following:
 6 (A) A National Institutes of Health institute.
 7 (B) A cooperative group of research facilities that has an
 8 established peer review program that is approved by a
 9 National Institutes of Health institute or center.
 10 (C) The federal Food and Drug Administration.
 11 (D) The United States Department of Veterans Affairs.
 12 (E) The United States Department of Defense.
 13 (F) The institutional review board of an institution located
 14 in Indiana that has a multiple project assurance contract
 15 approved by the National Institutes of Health Office for
 16 Protection from Research Risks as provided in 45 CFR
 17 46.103.
 18 (G) A research entity that meets eligibility criteria for a
 19 support grant from a National Institutes of Health center.
 20 (c) As used in this section, "covered individual" means an
 21 individual entitled to coverage under a state employee plan.
 22 (d) As used in this section, "nonparticipating provider" means
 23 a health care provider that has not entered into a contract with a
 24 state employee plan to serve as a participating provider.
 25 (e) As used in this section, "participating provider" means a
 26 health care provider that has entered into a contract with a state
 27 employee plan to provide health care services to covered
 28 individuals with an expectation of directly or indirectly receiving
 29 payment from the state employee plan.
 30 (f) As used in this section, "routine care cost" means the cost of
 31 medically necessary services related to the care method that is
 32 under evaluation in a clinical trial. The term does not include the
 33 following:
 34 (1) The health care service, item, or investigational drug that
 35 is the subject of the clinical trial.
 36 (2) Any treatment modality that is not part of the usual and
 37 customary standard of care required to administer or support
 38 the health care service, item, or investigational drug that is
 39 the subject of the clinical trial.
 40 (3) Any health care service, item, or drug provided solely to
 41 satisfy data collection and analysis needs that are not used in
 42 the direct clinical management of the patient.
 43 (4) An investigational drug or device that has not been
 44 approved for market by the federal Food and Drug
 45 Administration.
 46 (5) Transportation, lodging, food, or other expenses for the
 47 patient or a family member or companion of the patient that
 48 are associated with travel to or from a facility where a clinical
 49 trial is conducted.
 50 (6) A service, item, or drug that is provided by a clinical trial
 51 sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's state employee plan, including the sponsor of the clinical trial.

(g) As used in this section, "state employee plan" means one (1) of the following:

(1) A self-insurance program established under section 7(b) of this chapter to provide group health coverage.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

(h) A state employee plan must provide coverage for routine care costs that are incurred in the course of a clinical trial if the state employee plan would provide coverage for the same routine care costs not incurred in a clinical trial.

(i) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the state employee plan, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating providers and nonparticipating providers.

(j) This section does not do any of the following:

(1) Require a state employee plan to provide coverage for clinical trial services rendered by a participating provider.

(2) Prohibit a state employee plan from providing coverage for clinical trial services rendered by a participating provider.

(3) Require reimbursement under a state employee plan for services that are rendered in a clinical trial by a nonparticipating provider at the same rate of reimbursement that would apply to the same services rendered by a participating provider.

(k) This section does not create a cause of action against a person for any harm to a covered individual resulting from a clinical trial.

SECTION 2. IC 12-15-5-9.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: Sec. 9.2. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for

- 1 the research study; and
- 2 (iii) experience providing the type of care required for
- 3 the research study to a sufficient volume of patients to
- 4 maintain expertise; and
- 5 (C) to scientifically determine the best care method to
- 6 prevent, diagnose, or treat the cancer; and
- 7 (2) that is approved or funded by one (1) of the following:
- 8 (A) A National Institutes of Health institute.
- 9 (B) A cooperative group of research facilities that has an
- 10 established peer review program that is approved by a
- 11 National Institutes of Health institute or center.
- 12 (C) The federal Food and Drug Administration.
- 13 (D) The United States Department of Veterans Affairs.
- 14 (E) The United States Department of Defense.
- 15 (F) The institutional review board of an institution located
- 16 in Indiana that has a multiple project assurance contract
- 17 approved by the National Institutes of Health Office for
- 18 Protection from Research Risks as provided in 45 CFR
- 19 46.103.
- 20 (G) A research entity that meets eligibility criteria for a
- 21 support grant from a National Institutes of Health center.
- 22 (c) As used in this section, "routine care cost" means the cost of
- 23 medically necessary services related to the care method that is
- 24 under evaluation in a clinical trial. The term does not include the
- 25 following:
- 26 (1) The drug or device that is under evaluation in a clinical
- 27 trial.
- 28 (2) Items or services that are:
- 29 (A) provided solely for data collection and analysis and not
- 30 in the direct clinical management of an individual enrolled
- 31 in a clinical trial;
- 32 (B) customarily provided at no cost by a research sponsor
- 33 to an individual enrolled in a clinical trial; or
- 34 (C) provided solely to determine eligibility of an individual
- 35 for participation in a clinical trial.
- 36 (d) The Medicaid program must provide coverage for routine
- 37 care costs that are incurred in the course of a clinical trial if the
- 38 Medicaid program would provide coverage for the same routine
- 39 care costs not incurred in a clinical trial.
- 40 (e) The coverage that must be provided under this section is
- 41 subject to the terms, conditions, restrictions, exclusions, and
- 42 limitations that apply generally under the Medicaid program,
- 43 including terms, conditions, restrictions, exclusions, or limitations
- 44 that apply to health care services rendered by participating
- 45 providers and nonparticipating providers.
- 46 (f) This section does not do any of the following:
- 47 (1) Require the Medicaid program to provide coverage for
- 48 clinical trial services rendered by a participating provider.
- 49 (2) Prohibit the Medicaid program from providing coverage
- 50 for clinical trial services rendered by a participating provider.
- 51 (3) Require reimbursement for services that are rendered in

1 a clinical trial by a nonparticipating provider at the same rate
 2 of reimbursement that would apply to the same services
 3 rendered by a participating provider.

4 SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS
 5 A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY
 6 1, 2009]:

7 **Chapter 25. Coverage for Care Related to Clinical Trials**

8 **Sec. 1.** As used in this chapter, "care method" means the use of
 9 a particular drug or device in a particular manner.

10 **Sec. 2.** As used in this chapter, "clinical trial" means a Phase I,
 11 II, III, or IV research study:

12 (1) that is conducted:

13 (A) using a particular care method to prevent, diagnose, or
 14 treat a cancer for which:

15 (i) there is no clearly superior, noninvestigational
 16 alternative care method; and

17 (ii) available clinical or preclinical data provides a
 18 reasonable basis from which to believe that the care
 19 method used in the research study is at least as effective
 20 as any noninvestigational alternative care method;

21 (B) in a facility where personnel providing the care method
 22 to be followed in the research study have:

23 (i) received training in providing the care method;

24 (ii) expertise in providing the type of care required for
 25 the research study; and

26 (iii) experience providing the type of care required for
 27 the research study to a sufficient volume of patients to
 28 maintain expertise; and

29 (C) to scientifically determine the best care method to
 30 prevent, diagnose, or treat the cancer; and

31 (2) that is approved or funded by one (1) of the following:

32 (A) A National Institutes of Health institute.

33 (B) A cooperative group of research facilities that has an
 34 established peer review program that is approved by a
 35 National Institutes of Health institute or center.

36 (C) The federal Food and Drug Administration.

37 (D) The United States Department of Veterans Affairs.

38 (E) The United States Department of Defense.

39 (F) The institutional review board of an institution located
 40 in Indiana that has a multiple project assurance contract
 41 approved by the National Institutes of Health Office for
 42 Protection from Research Risks as provided in 45 CFR
 43 46.103.

44 (G) A research entity that meets eligibility criteria for a
 45 support grant from a National Institutes of Health center.

46 **Sec. 3.** As used in this chapter, "contracted provider" means a
 47 health care provider that has entered into an agreement under
 48 IC 27-8-11-3 with an insurer that issues a policy of accident and
 49 sickness insurance.

50 **Sec. 4.** As used in this chapter, "covered individual" means an
 51 individual entitled to coverage under a policy of accident and

1 sickness insurance.

2 Sec. 5. As used in this chapter, "noncontracted provider" means
3 a health care provider that has not entered into an agreement to
4 serve as a contracted provider.

5 Sec. 6. As used in this chapter, "policy of accident and sickness
6 insurance" has the meaning set forth in IC 27-8-5-1.

7 Sec. 7. As used in this chapter, "routine care cost" means the
8 cost of medically necessary services related to the care method that
9 is under evaluation in a clinical trial. The term does not include the
10 following:

11 (1) The health care service, item, or investigational drug that
12 is the subject of the clinical trial.

13 (2) Any treatment modality that is not part of the usual and
14 customary standard of care required to administer or support
15 the health care service, item, or investigational drug that is
16 the subject of the clinical trial.

17 (3) Any health care service, item, or drug provided solely to
18 satisfy data collection and analysis needs that are not used in
19 the direct clinical management of the patient.

20 (4) An investigational drug or device that has not been
21 approved for market by the federal Food and Drug
22 Administration.

23 (5) Transportation, lodging, food, or other expenses for the
24 patient or a family member or companion of the patient that
25 are associated with travel to or from a facility where a clinical
26 trial is conducted.

27 (6) A service, item, or drug that is provided by a clinical trial
28 sponsor free of charge for any new patient.

29 (7) A service, item, or drug that is eligible for reimbursement
30 from a source other than a covered individual's policy of
31 accident and sickness insurance, including the sponsor of the
32 clinical trial.

33 Sec. 8. (a) A policy of accident and sickness insurance must
34 provide coverage for routine care costs that are incurred in the
35 course of a clinical trial if the policy of accident and sickness
36 insurance would provide coverage for the same routine care costs
37 not incurred in a clinical trial.

38 (b) The coverage that must be provided under this section is
39 subject to the terms, conditions, restrictions, exclusions, and
40 limitations that apply generally under the policy of accident and
41 sickness insurance, including terms, conditions, restrictions,
42 exclusions, or limitations that apply to health care services
43 rendered by contracted providers and noncontracted providers.

44 (c) This section does not do any of the following:

45 (1) Require an insurer that issues a policy of accident and
46 sickness insurance to provide coverage for clinical trial
47 services rendered by a contracted provider.

48 (2) Prohibit an insurer that issues a policy of accident and
49 sickness insurance from providing coverage for clinical trial
50 services rendered by a contracted provider.

51 (3) Require reimbursement under a policy of accident and

sickness insurance for services that are rendered in a clinical trial by a noncontracted provider at the same rate of reimbursement that would apply to the same services rendered by a contracted provider.

Sec. 9. This chapter does not create a cause of action against a person for any harm to a covered individual resulting from a clinical trial.

SECTION 4. IC 27-13-7-20.2 IS ADDED TO THE INDIANA CODE AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 20.2. (a) As used in this section, "care method" means the use of a particular drug or device in a particular manner.**

(b) As used in this section, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

(c) As used in this section, "nonparticipating provider" means a health care provider that has not entered into an agreement described in IC 27-13-1-24.

(d) As used in this section, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

(1) The health care service, item, or investigational drug that is the subject of the clinical trial.

(2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.

(3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

(4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.

(5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility where a clinical trial is conducted.

(6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than an enrollee's individual contract or group contract, including the sponsor of the clinical trial.

(e) An individual contract or a group contract must provide coverage for routine care costs that are incurred in the course of a clinical trial if the individual contract or group contract would provide coverage for the same routine care costs not incurred in a clinical trial.

(f) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the individual contract or group contract, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by participating providers and nonparticipating providers.

(g) This section does not do any of the following:

(1) Require a health maintenance organization to provide coverage for clinical trial services rendered by a participating provider.

(2) Prohibit a health maintenance organization from providing coverage for clinical trial services rendered by a participating provider.

(3) Require reimbursement under an individual contract or a group contract for services that are rendered in a clinical trial by a nonparticipating provider at the same rate of reimbursement that would apply to the same services rendered by a participating provider.

(h) This section does not create a cause of action against a person for any harm to an enrollee resulting from a clinical trial.

- 1 SECTION 5. [EFFECTIVE JULY 1, 2009] (a) **IC 5-10-8-15, as**
2 **added by this act, applies to a state employee health plan that is**
3 **established, entered into, issued, delivered, amended, or renewed**
4 **after June 30, 2009.**
- 5 (b) **IC 12-15-5-9.2, as added by this act, applies to a Medicaid**
6 **risk based managed care contract that is entered into, delivered,**
7 **amended, or renewed after June 30, 2009.**
- 8 (c) **IC 27-8-25, as added by this act, applies to a policy of**
9 **accident and sickness insurance that is issued, delivered, amended,**
10 **or renewed after June 30, 2009.**
- 11 (d) **IC 27-13-7-20.2, as added by this act, applies to an individual**
12 **contract or a group contract that is entered into, delivered,**
13 **amended, or renewed after June 30, 2009.**
- 14 (e) **This SECTION expires July 1, 2014.**
 (Reference is to EHB 1382 as printed April 3, 2009.)

Conference Committee Report
on
Engrossed House Bill 1382

Signed by:

Representative Welch
Chairperson

Senator Gard

Representative Brown T

Senator Sipes

House Conferees

Senate Conferees